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## TRANSMITTAL FORM

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Total Number of Pages in This Submission

12

Application Number

10/574,163 ✓

Filing Date

June 15, 2006

First Named Inventor

LIU, Jin

Art Unit

TBD

Examiner Name

TBD

Attorney Docket Number

8028-005-US

### ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form  
☐ Fee Attached  
☐ Amendment/Reply  
☐ After Final  
☐ Affidavits/declaration(s)  
☐ Extension of Time Request  
☐ Express Abandonment Request  
☒ Information Disclosure Statement  
  
☐ Certified Copy of Priority Document(s)  
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Incomplete Application  
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under 37 CFR 1.52 or 1.53

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1. Self-addressed, stamped postcard  
2. Forms PTO/SB/08A & B  
3. Copies of reference as cited

Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|              |                         |          |        |
|--------------|-------------------------|----------|--------|
| Firm Name    | Catalyst Law Group, APC |          |        |
| Signature    |                         |          |        |
| Printed name | Michael B. Farber, Esq. |          |        |
| Date         | June 15, 2006           | Reg. No. | 32,612 |

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Substitute for form 1449/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

## **Complete if Known**

|                        |                |
|------------------------|----------------|
| Application Number     | 10/574,163     |
| Filing Date            | March 29, 2006 |
| First Named Inventor   | LIU, Jin       |
| Art Unit               | TBD            |
| Examiner Name          | TBD            |
| Attorney Docket Number | 8028-005-US    |

Sheet 1 of 3

## **NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No.† | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------|---|----------------|
|                    |           | J.B. MILLS et al., "Induction of Drug Metabolism Enzymes and MDR1 Using a Novel Human Hepatocyte Cell Line," J. Pharm. Exp. Therap. 309: 303-309 (2003).  |                |
| /V.A./             |           | G. LUO et al., "CYP3A4 Induction by Drugs: Correlation Between a Pregnane X Receptor Reporter Gene Assay and CYP3A4 Expression...", Drug Metab. Dispos. 30: 795-804 (2002).   |                |
| /V.A./             |           | A. MADAN et al., "Effects of Prototypical Microsomal Enzyme Inducers on Cytochrome P450 Expression in Cultured Human Hepatocytes, Drug Metab. Dispos. 31: 421-431 (2003).   |                |
| /V.A./             |           | G.T. TUCKER et al., "Optimizing Drug Development: Strategies to Assess Drug Metabolism/Transporter Interaction Potential - Toward...", Pharmaceutic. Res. 18: 1071-1080 (2001).   |                |
| /V.A./             |           | T.D. Bjorsson et al., "The Conduct of in Vitro and in Vivo Drug-Drug Interaction Studies: A PhRMA Perspective," J. Clin. Pharmacol. 43: 443-469 (2003).   |                |
| /V.A./             |           | F. Bost et al., "Inter-Alpha-Trypsin Inhibitor Proteoglycan Family-a Group of Proteins Binding and Stabilizing the Extracellular Matrix," Eur. J Biochem. 252: 339-346 (1998).  |                |
| /V.A./             |           | S. Yang et al., "Administration of Human Inter--Inhibitors Maintains Hemodynamic Stability and Improves Survival During Sepsis," Crit. Care Med. 30: 617-22 (2002).   |                |
| /V.A./             |           | K.E. Thummel & G.R. Wilkinson, "In Vitro and In Vivo Drug Interactions Involving Human CYP 3A," Ann. Rev. Pharmacol. Toxicol. 38: 389-430 (1998).   |                |
| /V.A./             |           | S. M. Cascio, "Novel Strategies for Immortalization of Human Hepatocytes," Artificial Orgs. 25: 529-538 (2001).   |                |
| /V.A./             |           | T. Kuroki & N. Huh, "Why Are Human Cells Resistant to Malignant Cell Transformation in Vitro?," Jpn. J. Cancer Res. 84: 1091-1100 (1993).   |                |

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| Examiner Signature | /Vera Afremova/ | Date Considered | 04/16/2008 |
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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |      | <b>Application Number</b>     | 10/574,163     |
|   |      | <b>Filing Date</b>            | March 29, 2006 |
|   |      | <b>First Named Inventor</b>   | LIU, Jin       |
|   |      | <b>Art Unit</b>               | TBD            |
|   |      | <b>Examiner Name</b>          | TBD            |
| <b>Sheet</b> 2  | of 3 | <b>Attorney Docket Number</b> | 8028-005-US    |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
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| /V.A./                          |                       | H. ZUR HAUSEN, "Oncogenic Herpesviruses" in J. Tooze ed., DNA Tumor Viruses ( Rev. Ed. 2, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1981), pp 747-798.   |                |
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| /V.A./                          |                       | J.A. DIPALO et al., "Progressive Changes Induced in Human and Mouse Cells by Human Papillomavirus Type 16 DNA," Cancer Cells 5: 253-257 (1987).   |                |
| /V.A./                          |                       | M.K. PATTERSON, Jr., "Measurement of Growth and Viability of Cells in Culture," Methods Enzymol., 58:141-152 (1979).  |                |
| /V.A./                          |                       | L.H. THOMPSON, "Mutant Isolation," Methods Enzymol. 58: 308-322 (1979).   |                |
| /V.A./                          |                       | S. A. LATT et al., "Microfluorometric Detection of Deoxyribonucleic Acid Replication in Human Metaphase Chromosomes," Proc. Natl. Acad. Sci. USA 70:3395 (1973).  |                |
| /V.A./                          |                       | S. A. LATT, "Fluorometric Detection of Deoxyribonucleic Acid Synthesis; Possibilities for Interfacing Bromodeoxyuridine Dye...", J. Histochem. Cytochem. 25:913-926 (1977).   |                |
| /V.A./                          |                       | P. PERRY & S. WOLFF, "New Giemsa Method for the Differential Staining of Sister Chromatids," Nature 261:156-158 (1974).   |                |
| /V.A./                          |                       | S. WOLFF (1981), "Measurement..." in E.C. Friedberg & P.C. Hanawalt, eds., DNA Repair: A Laboratory Manual of Research..., (Dekker, N.Y., 1981), vol. 1, Park B, pp. 575-586.   |                |
| /V.A./                          |                       | E.G. CORMIER et al., "CD81 Is an Entry Coreceptor for Hepatitis C Virus," Proc. Natl. Acad. Sci. USA 101:7270-7274 (2004).  |                |

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| <b>Examiner Signature</b> | /Vera Afremova/ | <b>Date Considered</b> | 04/16/2008 |
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| <b>Sheet</b> 3  | <b>of</b> 3 | <b>Attorney Docket Number</b> | 8028-005-US    |

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| Examiner Initials*                     | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
| /V.A./                                 |                       | J.P. SALIER et al., "The Inter--Inhibitor Family: From Structure to Regulation," Biochem. J. 351: 1-9 (1996).   |                |
| /V.A./                                 |                       | G. GRYNKIEWICZ et al., "A New Generation of Ca <sup>2+</sup> Indicators with Greatly Improved Fluorescence Properties," J. Biol. Chem. 260:3440-3450 (1985).  |                |
| /V.A./                                 |                       | E.J. STANBRIDGE et al., "Human Cell Hybrids: Analysis of Transformation and Tumorigenicity," Science 215:252-259 (1982).  |                |
| /V.A./                                 |                       | T. TSURIMOTO et al., "Stable Expression and Replication of Hepatitis B Virus Genome in an Integrated State in a Human...", Proc.Natl. Acad. Sci. USA 84:444-448 (1987).   |                |
| /V.A./                                 |                       | C.A. BRENNER et al. "Message Amplification Phenotyping (MAPING): A Technique to Simultaneously Measure Multiple mRNAs from Small...", Biotechniques 7: 1096-1103 (1989).  |                |
| /V.A./                                 |                       | Y.P. LIM et al., "Correlation Between Mortality and the Levels of Inter-alpha Inhibitors in Plasma of Severely Septic Patients," J. Infect. Dis. 188:919-926 (2003).  |                |
| /V.A./                                 |                       | K. NAWA et al., "Glucocorticoid-Dependent Expression of the Albumin Gene in Adult Rat Hepatocytes," J. Biol. Chem. 261:16883-16888 (1986).  |                |
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PATENT  
8028-005-US

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|                               |   |                                |
|-------------------------------|---|--------------------------------|
| In re Application of:         | ) | Examiner: To Be Assigned       |
|                               | ) |                                |
| Liu et al.                    | ) | Group Art Unit: To Be Assigned |
|                               | ) |                                |
| Serial No.: 10/574,163        | ) |                                |
|                               | ) | Docket No.: 8028-005-US        |
|                               | ) |                                |
| Filed: March 29, 2006         | ) | Date Mailed: June 15, 2006     |
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**INFORMATION DISCLOSURE STATEMENT**

Mail Stop: Information Disclosure Statement  
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Dear Sir:

This document is an Information Disclosure Statement to the above-cited patent application.

Attached is at least one form PTO/SB/08A/B listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b), the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.96, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned at (858) 450-0099 x302 so that any deficiencies can be remedied.

This Information Disclosure Statement is being submitted within three months of the filing date of the above-identified patent application. Accordingly, no fee is due for the filing of this Information Disclosure Statement under 37 C.F.R. § 1.97(b)(1).

A copy of each document is enclosed, except for issued United States patents and published United States patent applications pursuant to 37 C.F.R. § 1.98(a)(2)(ii). Some of the documents may have markings thereon. No significance is to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import, as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the prosecution of this application; and (2) represented on any patent which may issue on the application. Applicant respectfully

requests that copies of the forms PTO/SB/08A/B, as considered and initialed by the Examiner, be returned with the next communication.

U.S. Patent No. 5,665,589 to Harris et al., issued on September 9, 1997.

U.S. Patent No. 6,046,050 to Strauss et al., issued on April 4, 2000.

U.S. Patent No. 6,107,043 to Jauregui et al., issued on August 22, 2000.

U.S. Patent No. 6,653,105 to Triglia et al., issued on November 25, 2003.

U.S. Patent Application Publication No. 2002/0045262 by Prachumsri, published on April 18, 2002.

PCT Patent Application Publication No. WO 99/55853 by Fukaya et al., published on November 4, 1999, which describes a novel immortalized hepatic cell line originating in normal human (preferably human fetal) cells, a process for producing this cell line; a method for screening compounds or salts thereof capable of inhibiting or promoting the activity of an enzyme participating in the metabolism of a biological foreign matter in the liver, inhibiting or promoting the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, or inhibiting or promoting the induction of the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, the process involving using the above-mentioned cell line. The application further describes compounds capable of inhibiting or promoting the activity of an enzyme participating in the metabolism of a biological foreign matter in the liver, compounds capable of inhibiting or promoting the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, compounds capable of inhibiting or promoting the induction of the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, or salts of these compounds



obtained by the above screening method. The cell line is described as useful in, for example, screening compounds having preventive/therapeutic effects on liver failure.

A publication, J.B. Mills et al., "Induction of Drug Metabolism Enzymes and MDR1 Using a Novel Human Hepatocyte Cell Line," J. Pharm. Exp. Therap. 309: 303-309 (2003).

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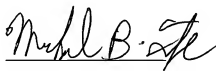
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Respectfully submitted,

Date: June 15, 2006

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